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SECTION 10

510(k) SUMMARY K020072 1/3

This 510(k) summary of safety and effectiveness for the Athos Long Pulsed Nd:YAG laser is submitted in accordance with the requirements of SMDA 1990 and follows Office of Device Evaluation guidance concerning the organization and content of a 510(k) summary.

Applicant: Quantel Medical

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Contact Person: Mr. Jean Abascal

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Preparation Date: December 2001
(of the Summary)

Device Name: Athos laser

Common Name: Nd:YAG Surgical Laser (Long Pulse Nd:YAG laser)

Classification Name: Laser surgical instrument for use in general and plastic surgery and in dermatology (see: 21 CFR 878.4810).
Product Code: GEX
Panel: 79

Predicate device: The Athos Long Pulse Nd:YAG laser

Device description: The Athos laser emits a beam of coherent light at 1064 microns.

Indications: The Athos laser is intended for hair removal (destruction of hair follicles) in all skin types and for soft tissue applications.

The soft tissue applications are for the coagulation, photocoagulation, incision/excision, ablation, and vaporization of soft tissues including skin, cutaneous tissue, subcutaneous tissue, striated and smooth tissue, muscle, cartilage meniscus, mucous membrane, lymph vessels and nodes, organs and glands.

Dermatology: In addition to the tissue types cited, pigmented lesions to reduce lesion size; for patients with lesions that would potentially benefit from aggressive treatment; for patients with lesions that have not responded to other laser treatments.

Endoscopic/Laparoscopic General Surgery: Incision/excision and cutting, ablation, coagulation/hemostasis of soft tissue in endoscopic, laparoscopic surgery applications, including but not limited to cholecystectomy, appendectomy, vagotomy, and pyloromyotomy.

Gastroenterology: Tissue ablation and hemostasis in the GI tract; esophageal neoplastic obstructions including squamous cell carcinoma and adenocarcinoma; GI hemostasis; including varices, esophagitis, esophageal ulcer, Mallory-Weiss tear, gastric ulcer, angiodysplasia, stomal ulcers, non-bleeding ulcers gastric erosions GI tissue ablation including benign and malignant neoplasms, angiodysplasia; polyps, ulcer, colitis, and hemorrhoids.

General Surgery: Soft tissue in general surgery applications, skin incisions, tissue dissection, excision of external tumors and lesions, complete or partial resection of internal organs, tumors, lesions, tissue ablation, vessel coagulation.

Gynecology: Treatment of menorrhagia by photocoagulation of thee endometrial lining of the uterus, ablation of endometrial implants and/or peritoneal adhesions, soft tissue excision procedures such as conization of the cervix, intra-uterine gynecologic procedures where cutting, ablation and/or vessel coagulation may be indicated including submucous fibroids, benign endometrial polyps, uterine septum.

Head and Neck/Otorhinolaryngology (ENT): For the coagulation, photocoagulation, incision/excision, ablation, and vaporization of soft tissue.

Hemostasis during surgery: Adjunctive coagulation and hemostasis (control of bleeding) during surgery (endoscopic, laparoscopic, and open procedures).

Neurosurgery: Hemostasis of pituitary tumor, meningioma, hemagioblastoma, AVMs, glioma, glioblastoma, astrocytoma, oligodendroglioma.

Oculoplastics: Incision, excision, vaporization, ablation, and coagulation of soft tissues in oculoplastic procedures such as operations on the lacrimal system, operation on the eyelids, removal of biopsy or orbital tumors, enucleation of the eyeball, exteneration of orbital contents.

Orthopedics: Incision, excision, cutting, ablation and/or hemostasis of intra-articular tissue in orthopedic surgical and arthroscopic applications.

Plastic Surgery: Incision, excision, cutting, coagulation, and vaporization soft tissue.

Pulmonary/Thoracic Surgery: Palliative treatment of benign and malignant pulmonary airway obstructions including squamous cell carcinoma, adenocarcinoma, carcinoid, benign tumors, granulomas, and benign strictures.

Thoracic Surgery: Incision, excision, cutting, coagulation, and vaporization of soft tissue, including lung tissue, in thoracic applications including but not limited to isolation of vessels for endarterectomy and/or by-pass grafts, wedge resections, thoractomy, formation of pacemaker pockets.

Urology: All applications including superficial urinary bladder tumors, invasive bladder carcinoma, urethral strictures, and lesions of the external genitalia (including condyloma accuminata).

The Athos laser will be labeled as a prescription device:

CAUTION: Federal (US) law restricts the use of this device to licensed professionals.

Performance Data: None required.

CONCLUSION:

Based on the information in the notification Quantel Medical concludes that the Athos laser which is the subject of this notification is substantially equivalent to the Athos laser described in K001704 under the conditions of intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR - 9 2002

Quantel Medical
c/o Mr. Roger W. Barnes
342 Sunset Bay Road
Hot Springs, AR 71913

Re: K020072
Trade/Device Name: Athos Laser
Regulation Number: 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: II
Product Code: GEX
Dated: January 7, 2002
Received: January 9, 2002

Dear Mr. Barnes:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SECTION 7

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K020072

Device Name: Athos laser (Nd:YAG Long-pulsed laser)

Indications for Use Statement:

The Athos laser is intended for hair removal (destruction of hair follicles) in all skin types and for soft tissue applications.

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(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation

Prescription Use ✓ OR Over-The Counter Use
(Per 21 CFR 801.109)

Indications for Use Statement: (Continued)

General Surgery: Soft tissue in general surgery applications, skin incisions, tissue dissection, excision of external tumors and lesions, complete or partial resection of internal organs, tumors, lesions, tissue ablation, vessel coagulation.

Gynecology: Treatment of menorrhagia by photocoagulation of thee endometrial lining of the uterus, ablation of endometrial implants and/or peritoneal adhesions, soft tissue excision procedures such as conization of the cervix, intra-uterine gynecologic procedures where cutting, ablation and/or vessel coagulation may be indicated including submucous fibroids, benign endometrial polyps, uterine septum.

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The Athos laser will be labeled as a prescription device as follows:

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CAUTION: Federal (US) law restricts the use of this device to licensed professionals

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K020072